

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

AP	PLICATION NO.		FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,847 05/29/20		05/29/2001	Robert Chalifour	14445-501 CIP	8081	
	21559	7590	04/23/2003			•
CLARK & ELBING LLP					EXAMINER	
	101 FEDERAL STREET BOSTON, MA 02110			TURNER, SHARON L		
					ART UNIT ·	PAPER NUMBER
					1647 DATE MAILED: 04/23/2003	19

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
	09/867,847	CHALIFOUR ET AL.					
Offic Action Summary	Examiner	Art Unit					
	Sharon L. Turner	1647					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status							
1) Responsive to communication(s) filed on <u>1-23</u>	<u>-03</u> .						
2a) ☐ This action is FINAL . 2b) ☑ Thi	s action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
	Claim(s) 1-8,12-17 and 21-39 is/are pending in the application.						
	4a) Of the above claim(s) <u>21-39</u> is/are withdrawn from consideration.						
	Claim(s) is/are allowed.						
<u></u>	☐ Claim(s) 1-8 and 12-17 is/are rejected.						
 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) <u>1-8,12-17 and 21-39</u> are subject to res 	striction and/or alaction requirem	oont					
8)⊠ Claim(s) <u>1-8,12-17 and 21-39</u> are subject to res Application Papers	striction and/or election requirem	iciii.					
9) The specification is objected to by the Examiner.							
10)⊠ The drawing(s) filed on is/are: a)□ accepted or b)⊠ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12)☐ The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) ☐ All b) ☐ Some * c) ☐ None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents	s have been received in Applicat	ion No					
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 							
14)⊠ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) ☐ The translation of the foreign language provisional application has been received. 15)☑ Acknowledgment is made of a claim for domestic prionty under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.	5) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152)					

Art Unit: 1647

DETAILED ACTION

1. The preliminary amendments filed 9-21-01, 12-9-02, and 1-3-03 have been entered into the record and have been fully considered.

2. Claims 9-11 and 18-20 are canceled. Claims 1-8, 12-17 and 21-39 are pending.

Sequence Compliance

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

In particular, the specification and Figures 1-3 and 7 reference particular sequences that are not properly referenced by an appropriate SEQ ID NO. Correction is required.

Drawings

4. The drawings are objected to because the legend, i.e., "Figure X" is illegible. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

5. The disclosure is objected to because of the following informalities: Figures 1-3 and 7 reference amino acid sequences where no appropriate SEQ ID NO: is referenced within the Brief description of the drawings.

Appropriate correction is required.

Application/Control Number: 09/867,847 Page 3

Art Unit: 1647

Priority

6. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No.______" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

In particular, reference to the 09/724,842 application should be made within the first paragraph.

Election/Restriction

Applicant's election with traverse of Group I, claims 1-8 and 12-17 to the extent of methods of treating or preventing by administration with a peptide of SEQ ID NO:15, in Paper No. 14(12-31-02) is acknowledged. The traversal is on the ground(s) that the claims as amended recite SEQ ID NO:15 and that other particular amino acids contain the relevant sequence and may be subject to rejoinder. Applicants also argue that the peptides are related, that more than one sequence may be searched when no undue burden exists and that instantly there is no burden of search of the multiple peptide sequences.

Applicant's arguments have been fully considered but are not found persuasive.

Although particular claims have been amended to narrow the scope to SEQ ID NO:15, the claims remain drawn to alternative peptides that differ in primary structures (sequence) as recited in the claims and as evidenced by their different sequence identifiers. The peptides lack common structure and accordingly are capable of different uses, effects and functions. Moreover, the claims are drawn to the use of the

Art Unit: 1647

examination of more than a single structure bears an undue burden on the Examiner. In addition, the different sequences cover substantive art and obviousness issues that separately apply to the patentably distinct peptides and their uses. A search for any single sequence would not reveal all relevant art to any other sequence. Further, a reference against any particular peptide would not necessarily be a reference to any other with respect to 35 USC 102 or 103. Therefore the peptides are not proper species and lack unity of invention in accordance with MPEP 803.02 as they lack common structure. Moreover, it is noted that the inventions need only be independent or distinct in accordance with MPEP 803, see also discussions of the terms in MPEP 802.01-02. The different peptides are both independent and distinct as set forth.

8. Claims 21-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14.

Double Patenting

9. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory

Art Unit: 1647

double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-8 and 12-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 46-56, 58-64, and 66-109 of copending Application No. 09/724,842. Although the conflicting claims are not identical, they are not patentably distinct from each other because the comprised peptides overlap with instantly elected SEQ ID NO:15. In particular it is noted that the claims similarly recite methods of preventing and treating amyloid related diseases including via administration with all-D peptides. It is noted that the peptides either share the common structure of SEQ ID NO:15 or are identical. In particular SEQ ID NO's 13 and 21 share the same structure and length as SEQ ID NO:15. Moreover, the claims similarly recite the administration of the same peptides with the same alternative N'terminal and C'terminal modifications as recited for example in instant claims 4-8 and 12-17. The administration is of the same compounds to the same individuals for the same purpose and thus inherently share all functional components as recited such as inducing an immune response, eliciting the production of antibodies, interacting with an amyloid protein and thereby preventing or reducing neurodegeneration, cellular toxicity and amyloid fibril formation. Thus, the co-pending claims render the instant claims obvious to the skilled artisan.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

11. Claims 1-8 and 12-17 are objected to as reciting an improper Markush Group.

M.P.E.P. 803.02 states that:

Since the decisions in In re Weber, 198 USPQ 328 (CCPA 1978); and In re Haas, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); Ex Parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.

In instant case the encompassed peptides differ substantially in structure and are capable of different use, with different modes of operation, different function and different effects. Therefore the peptides lack unity of invention.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1-8 and 12-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling as supported in the literature for reducing beta-amyloid plaque burden in cortical regions of PDAPP transgenic mice via administration of AN1792 (human Aβ1-42), rodent Aβ1-42 and Aβ1-5 conjugated to sheep anti-mouse IgG as exemplified and disclosed for example in Schenk et al., WO99/27944 published 10 June 1999, does not reasonably provide enablement for preventing or treating amyloid related disease, particularly in a human patient or for preventing or treating such diseases with the breadth of peptides claimed. In particular the breadth of the

Art Unit: 1647

peptides as claimed encompasses all peptides capable of providing for the claimed functional effects that are in a portion, D-amino acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to make and use the invention commensurate in scope with these claims.

The specifications disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without undue experimentation. The factors relevant to this discussion include the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims.

The claims are drawn to a method for treatment and prevention of amyloid related diseases via administration of D-amino acid peptides. The specification fails to exemplify any such treatment but references Schenk et al., 1999 Nature 400:173-177 as a basis for such prevention or treatment. Schenk teaches that the administration of particular polypeptides is able to reduce beta-amyloid levels within the brains of mice that are transgenic for PDAPP. These mice exhibit Alzheimer's type over production and build up of beta-amyloid within the brain. However, as recognized in the art, these mice do not exhibit Alzheimer's disease as in humans or plaque morphology and components which are the same as in humans, Alzheimer's disease, Down's Syndrome or other amyloidogenic diseases, see in particular Schenk et al., Nature, 400:173-77, 1999 (IDS), Games et al., Nature 373(6514):523-7, 1995 (IDS) and Chen et al., Progress in Br. Res., 117:327-34, 1998. Thus, the model system used is not recognized as providing for teachings that are predictive of the results that would be

expected for the full scope of the claims, including for any amyloid related disease or for such diseases in humans. For example, the art recognizes that such in vivo models are not readily correlated to the human in vivo case. In particular, the art teaches a lack of correlation of beneficial effects shown in the mouse model system in humans, see in particular Munch et al., J. Neural Transmission, 2002 July, 109(7-8):1081-87. Specifically, treatments effective in mice were shown to evoke neurotoxicity when practiced in humans. Thus, for the aforementioned reasons treatment of humans does not appear to be commensurate in scope with the claims.

Moreover, the model system does not fairly teach that the treatment is effective to prevent the onset of disease. Alternatively, the teachings exhibit a reduction of pathogenic characteristics in Alzheimer-like pathology, but fail to teach the prevention of plaque development in animals. As evidence, the Examiner notes that all PDAPP mice exhibited plaques regardless of treatment regime. Even the most effective treatments were only effective to reduce the plaque burden in animals, not prevent it.

The method is based upon findings that show particular strategies of targeting plaque removal via antigen administration. Evidence that such therapy can be effective in the removal of amyloid plaque burden is exhibited by Lemere et al., Society for Neuroscience Abstracts, vol. 25, part I, Abstract 519.6, 29th Annual Meeting 10/23-10/28, 1999 using antigen Aβ1-40 and Schenk, Nature, 400:173-177, 1999 (IDS) using antigen Aβ1-42. Similarly Nordstett and Kiessling as set forth below teach treatment of Alzheimer's disease and amyloid plaque deposits via administration of the KVLFF

sequence. However, what these references do not teach is the relative ability of other alternative peptides to achieve such effects.

The skilled artisan readily recognizes that protein chemistry is an unpredictable area of biotechnology. Proteins with deletion, insertion or substitution/replacement of single amino acid residues may lead to both structural and functional changes in biological activity and immunological recognition, see in particular Skolnick et al., Trends in Biotech., 18(1):34-39, 2000. For example, Jobling et al, Mol. Microbiol., 1991, 5(7):1755-67 teaches a panel of single amino acid substitutions by oligonucleotide directed mutagenesis which produce proteins that differ in native conformation, immunological recognition, binding and toxicity. The skilled artisan further recognizes that immunological responses may depend upon the structural characteristics (conformation) of the particular protein (amino acid sequence) targeted. Thus, both biological function and immunological recognition are unpredictable properties which must be experimentally determined. Further it is noted, that for particularly small peptides, conjugation appears to be required for promoting an effective immune response.

These concepts are exemplified within Schenk WO99/27944. For example, the specification discloses experimentation using a group of human Aβ peptide sequences consisting peptides of 1-5, 1-12, 13-28, and 33-42 conjugated to sheep anti-mouse IgG, see in particular pp. 62, lines 25-32. Yet only the conjugated fragment of Aβ1-5 was effective to reduce plaque burden in PDAPP mice, and only within the cortex, see in particular pp. 64, lines 30-31. Thus, the specification exemplifies the unpredictable

nature of providing prevention or treatment with variable but even highly related peptides. Thus, the Schenk publication evidences the unpredictability and variability in the effectiveness of peptide immunogen constructs in effecting amyloid plaque removal or treatment of amyloid related diseases. Thus, the specification does not enable the broad scope of the claims which encompass a multitude of analogs or equivalents because the specification does not teach which residues can or should be modified such that the polypeptides retain sufficient structural similarity to evoke immune responses that would provide for treatment or preventative effects. The specification provides essentially no guidance as to which of the nearly infinite possible choices is likely to be successful and the skilled artisan would not expect functional conservation among homologous or variable sequences. The artisan cannot predict the protective epitope structures without further undue experimentation.

Finally, the claims recite the use of an antigenic all-D peptide via it's functional characteristics and not by it's particular amino acid structure. The functions to be provided include a sufficient response to produce antibodies, induce an immune response, prevent or reduce amyloid-induced neurodegeneration or amyloid fibril formation, interact with an amyloid protein, and the ability to prevent or reduce amyloid-induced cellular toxicity. Yet the specification does not exemplify which peptides are particularly able to produce such effects. Thus, the claims are akin to a single means claim, i.e., where a means recitation does not appear in combination with another recited element of means and is subject to an undue breadth rejection under 35 USC 112, first paragraph because the specification at most would only disclose those means

known to the inventor at the time of the invention, see in particular MPEP 2164.08(a). While the artisan may recognize particular peptides that have been shown to be effective, such is not commensurate with the scope of all peptide sequences that are as yet not identified but which are capable of producing the claimed effects. The specification fails to provide a suitable methodology for determining or predicting the success of peptide sequences for producing the requisite effects and thus the enablement provided by the specification is not commensurate with the scope of the claims.

Therefore, applicants have not provided sufficient guidance to enable one skilled in the art to make and use the claimed derivatives in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes which can be made and still maintain activity/utility is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See Exparte Forman, 230 USPQ 546 (Bd. Pat. App. & Int. 1986).

In view of the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue experimentation to make and use the claimed invention.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1647

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 1-8 and 12-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947).

MPEP 2173.05(a) states that:

While a term used in the claims may be given a special meaning in the description of the invention, generally no term may be given a meaning repugnant to the usual meaning of the term. In re Hill, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). However, it has been stated that consistent with the well-established axiom in patent law that a patentee is free to be his or her own lexicographer, a patentee may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings. Hormone Research Foundation Inc. v. Genentech Inc., 904 F.2d 1558, 15 USPQ2d 1039 (Fed. Cir. 1990). Accordingly, when there is more than one definition for a term, it is incumbent upon applicant to make clear which definition is being relied upon to claim the invention. Until the meaning of a term or phrase used in a claim is clear, a rejection under 35 U.S.C. 112, second paragraph is appropriate. It is appropriate to compare the meaning of terms given in technical dictionaries in order to ascertain the accepted meaning of a term in the art. In re Barr, 444 F.2d 588, 170 USPQ 330 (CCPA 1971).

Claims 1-8 and 12-17 use the term "all-D" which is variably defined in the specification at p. 26, lines 22-25. Thus the use of the term "all-D" in claims 1-8 and 12-17 is indefinite as to what percentage of the molecule is intended to be of D-amino acids. The art accepted meaning of "all" is every, but the use of the term may mean anywhere from 50%-100% D-amino acids as defined in the specification. Thus, the

metes and bounds of the amino acids which are required to be D-amino acids is indefinite to the artisan. Clarification is required.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in-

the treaty defined in section 351(a).

- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under
- 17. Claims 1-8 and 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Nordstedt et al., WO97/21728 published 19 June 1997 and under 35 U.S.C. 102(e) as being anticipated by Nordstedt et al., US Patent No. 6,331,440 filed June 10, 1998. These rejections are set forth in conjunction as the references are cumulative. However, as noted, the references apply under different statutes.

Nordstedt et al., teach peptide binding sequences of beta amyloid useful as medicaments and as tools for identification of substances to be used in the treatment or prevention of amyloidosis, see in particular Abstract and Introduction. In particular peptides comprising the peptide KLVFF are disclosed as useful for treatment of Alzheimer's disease, see in particular Summary of the invention and Detailed description of the invention. As noted therein, all of the amino acids may be either of D-

Art Unit: 1647

or L-isomers. In addition, as represented by R1 and R2 in the formula R1-A'-Y'-Leu-X'-Z'-B-R2, the N-terminal substituents may be of H (hydrogen) or -CO-R3 bonded at the amino group of A'. Also, the C-terminal substituents may be of hydrogen OR4 or NR5R6 bonded to the carboxyl group of the carboxy terminal B' as set forth in the Detailed description of the invention. As substituted at the N' and C'terminus the substituents of Nordstedt are the same as claimed, i.e., hydrogen (hydroxy), alkyl (alkoxy), cycloalkyl, aryl (aryloxy), or (substituted amino), (as claimed). The substituents constitute acid functional groups and pharmaceutically acceptable salt or ester forms suitable for administration, see in particular Detailed description of the invention for the treatment and prevention of fibril formation of human amyloid protein As in Alzheimer's disease. The peptides are administered to the same patient groups in the same form and for the same purpose as claimed. Such peptides are extensively recognized as capable of eliciting an immune response, see in particular Schenk et al., of record. Thus, all functional limitations are necessarily provided absent convincing factual evidence to the contrary. Therefore, the reference teachings anticipate the claimed invention.

18. Claims 1-8 and 12-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Kiessling et al., US Patent No. 6,022,859 filed February 8, 2000.

Kiessling et al., teach peptide inhibitors of beta-amyloid toxicity, see in particular Abstract. The peptide comprises the recognition element sequence KLVFF. The peptide disrupts beta-amyloid aggregation and interferes with its toxicity, thereby providing a therapeutic reagent for treating Alzheimer disease patients, see in particular Brief Summary of the Invention. The peptide maybe substituted or unsubstituted including via alkyl, alkoxy, hydroxy and carboxy, see in particular column 4. The

preparation may be for pharmaceutical use and may be accordingly modified via buffering agents including for pharmaceutically acceptable salt or ester forms, see in particular columns 5-6. The peptides are administered to the same patient groups in the same form, for the same purpose as claimed. Such peptides are extensively recognized as capable of eliciting an immune response, see in particular Schenk et al., of record. Thus, all functional limitations are necessarily provided absent convincing factual evidence to the contrary. Therefore, the reference teachings anticipate the claimed invention.

Status of Claims

- 19. No claims are allowed.
- 20. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D. April 8, 2003

BARY KUNZ

NO PATENT EXAMINER

TECHNOLOGY CENTER 1600